

July 2006



Nevada State Board of Pharmacy

555 Double Eagle Ct, Suite 1100, Reno, NV 89521-2957
www.state.nv.us/pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Board Members

Joseph R. Kellogg, RPh, Henderson.....President
Leo Basch, RPh, Las Vegas Treasurer
Keith Macdonald, RPh, Carson City..... Board Member
Raymond J. Seidlinger, RPh, Las Vegas..... Board Member
Kathryn Craven, RPh, Las Vegas..... Board Member
J. David Wuest, RPh, Reno..... Board Member
Ann Peterson, Reno Board Member

Schedule of 2006 Board Meetings

July 19-20..... Las Vegas
September 6-7 Reno
October 25-26 Las Vegas
December 6-7..... Reno

Pseudoephedrine Restrictions Signed Into Law

As part of the renewal of the USA Patriot Act, the federal government enacted nationwide restrictions on the sale of pseudoephedrine, ephedrine, and phenylpropanolamine designed to curtail the production of methamphetamine. The first phase, effective April 8, 2006, requires that products containing the above mentioned products be placed behind a counter or locked in a cabinet as well as limits a purchase to 3.6 grams per day or 9 grams per month. (Note: Nevada state law limits the daily purchase to 3 grams.) Also, non-liquid dosage forms must be unit-dose or blister packaged. Beginning September 30, 2006, the buyer must show photo identification and sign a log book.

Recent studies show that the number of people seeking help for methamphetamine abuse is up some 300% from 10 years ago. Hopefully these restrictions will have some impact.

Does a Prescription Die With the Physician?

Occasionally a pharmacist will be asked to fill or refill a prescription that was written by a physician who has since passed away, retired, or moved out of the community or has had their license suspended or revoked. Can this request be honored? In short, the answer is **no**. Food

and Drug Administration recognizes that a prescription given to a patient by a practitioner has an established physician/patient relationship. Once this relationship is severed, the prescription loses its validity since the practitioner is no longer available to oversee the use of the prescribed drug.

Having said that, as in so many circumstances that pharmacists face every day, the use of professional judgment to take care of the patient in a reasonable manner is prudent practice. In this spirit, the pharmacist may need to exert a bit more effort to help the patient. Examples would be calling the old office to see where the patient records have been moved, calling to see if another physician has taken over the patient records, helping the patient get an appointment with another physician, or asking the new physician to authorize an interim supply. In most cases (controlled substances being the exception) the pharmacist may provide an interim supply of maintenance medication to allow the patient time to reestablish with another physician. Nevada State Board of Pharmacy staff feels that a 30-day supply is reasonable.

New CE Options

The Board of Pharmacy, at a recent meeting has authorized accredited continuing education (CE) by two new sources. The first is through the National Association of Boards of Pharmacy® and is called the Pharmacist Self-Assessment Mechanism® (PSAM®). PSAM is a self-assessment tool available online at www.nabp.net that assists pharmacists in obtaining objective feedback on their knowledge of current practice therapies. The Board recognizes the ever-changing concepts in pharmaceutical care as well as the constant introduction of new therapeutic agents. PSAM allows a pharmacist to become aware of his or her individual strengths and weaknesses and then to target areas that would improve professional competency.

The Board will allow four hours of accredited CE for those taking PSAM.

The second new source of CE involves CE accredited by boards of other disciplines (medicine, nursing, etc). The Board recognizes that coursework that meets the standard

Continued on page 4



Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex[®] tablets, who recently released Zanaflex Capsules[™] (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune[®] (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL[®] (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated

products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

Preventing Errors Linked to Name Confusion



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- ◆ Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- ◆ Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- ◆ Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.

Compliance News

Compliance News to a particular state or jurisdiction should not be assumed to be the law of such state or jurisdiction.)



- ◆ When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- ◆ Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- ◆ Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- ◆ Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- ◆ Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- ◆ Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- ◆ Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- ◆ Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- ◆ Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006,

for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.deadiversion.usdoj.gov/meth/cma2005.htm.

Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

- (a) Each partial filling is recorded in the same manner as a refilling,
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
- (c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

Continued from page 1

of relevance to pharmacy should be awarded accredited CE for pharmacists as well. To obtain credit for a CE program accredited by another professional board, you must submit to the Board of Pharmacy an outline of the program at least 60 days prior to attending the course. The Board will then assess the program as to its relevance to pharmacy and assign credit accordingly. Obviously, sections on “how to run your medical office” or “how to seat a crown” will not be assigned credit.

Changes to Schedule II Prescriptions

The Board office often receives calls regarding what can be changed on a Schedule II prescription. To clarify, after consulting with the prescribing practitioner (you must speak directly to the practitioner, **not** his agent), the pharmacist may modify or add the following:

- ♦ date of issue – may be added but **not** changed;
- ♦ patient’s address;
- ♦ drug strength;
- ♦ drug dosage form;
- ♦ drug quantity – may be modified in conjunction with change in strength only, not to exceed the original total dosage prescribed; and
- ♦ directions for use.

A pharmacist may **never** change the name of the drug (except to generic when appropriate), name of the patient, or the signature of the practitioner.

Now What?

Staff had an interesting call in May 2006 from an institutional pharmacist whose facility had admitted a patient with medications that included contraband drugs. What was he to do with them? Keep them in the pharmacy and return them to the patient upon discharge? Call the police? Destroy them? Staff’s advice is to call local authorities and turn them over; however, it is probably wise to inventory the drugs with the officer picking them up and to obtain his signature as well as that of the pharmacist. Just such a procedure should probably be incorporated into pharmacy policy and procedure for future reference.

When a Pharmacist May Refuse to Fill a Prescription

On May 4, 2006, the Board’s new regulation regarding when and how a pharmacist may refuse to fill a prescription became effective. Under the new regulation, a pharmacist may refuse to fill a prescription if he or she determines in his or her professional judgment that the prescription might harm the medical health of a patient, might be fraudulent, or might not be for a legitimate medical purpose. If a pharmacist makes such a judgment, he or she must contact the prescriber to attempt to resolve the concern. If the pharmacist cannot immediately contact the prescriber, the pharmacist may return the prescription to the patient, may retain the prescription, may make a copy of the prescription and return it, or may dispense up to a three-day supply (except for Schedule IIs), or any combination of these possibilities.

If the contact with the prescriber verifies the pharmacist’s concern, the pharmacist may not dispense the prescription. If the contact with the prescriber resolves the pharmacist’s concern, the pharmacist may dispense the prescription. This new regulation does not allow a pharmacist to decline to fill a prescription for non-professional reasons such as the pharmacist’s religious, moral, or philosophical convictions. These questions have been left to the Nevada Legislature.

Page 4 – July 2006

The *Nevada State Board of Pharmacy News* is published by the Nevada State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Larry Pinson, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor

Larissa Doucette - Editorial Manager

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056
NEVADA STATE BOARD OF PHARMACY